UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO: *State of Montana* v. *Abbot Labs., Inc., et al.*, D. Mont. Case No. CV-02-09-H-DWM AND *State of Nevada* v. *American Home Prods. Corp., et al.*, D. Nev. Case No. CV-N-02-0202-ECR	Civil Action No. 01-12257-PBS Judge Patti B. Saris

STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF SCHERING-PLOUGH CORPORATION'S AND WARRICK PHARMACEUTICALS CORPORATION'S MOTION FOR SUMMARY JUDGMENT AS TO NEVADA AND MONTANA ACTIONS

Pursuant to Local Rule 56.1, Defendants Schering-Plough Corporation ("Schering") and Warrick Pharmaceuticals Corporation ("Warrick") submit this concise statement of the material facts of record as to which there is no genuine issue to be tried, in support of their motion for summary judgment.[1]

I. AWP AND THE GENERIC MARKET

A. AWP

1. Average wholesale price, or "AWP," is a negotiation benchmark that has been used

[1] To the extent relevant, Warrick and Schering incorporate by reference the Statements of Undisputed Material Facts submitted jointly by all Defendants in support of their joint motions for summary judgment as to the Nevada and Montana Complaints.

in the pharmaceutical industry for decades. *See* Diederich Decl. Ex. 1 (Declaration of Harvey J. Weintraub ("Weintraub Decl.") at ¶ 25.[2]

2. Warrick understood AWP to be a benchmark or list price. *See id.*; Diederich Decl. Ex. 2 (Weintraub Dep. Tr.) at 21; Diederich Decl. Ex. 3 (Sherman Dep. Tr.) at 21.

B. Warrick and the Market for Generic Drugs.

3. Warrick manufacturers generic drugs. *See* Montana 2d Am. Compl. ¶ 98; Nevada Am. Compl. ¶ 66.

4. In the generic industry, unlike the brand industry, the competing products are identical. Diederich Decl. Ex. 1 (Weintraub Decl.) ¶ 14-17.

5. Given the presence of perfect product substitutes in the generic market, prices can change often and generally decrease over time. *See* Diederich Decl. Ex. 1 (Weintraub Decl.) ¶ 15, Affidavit of Sumanth Addanki ("Addanki Aff.") Attachment ¶¶ 34-35; Diederich Decl. Ex. 3 (Sherman Tr.) at 65-66.

6. The pricing of Warrick's products varies according to market conditions and can change regularly. *See* Diederich Decl. Ex. 1 (Weintraub Decl.) ¶ 17; Diederich Decl. Ex. 2 (Weintraub Dep. Tr.) at 41; Diederich Decl. Ex. 3 (Sherman Dep. Tr.) at 66-67.

7. Warrick competed in the marketplace by establishing accounts and then meeting, but typically not beating, the prices offered by competitors. *See* Diederich Decl. Ex. 1 (Weintraub Decl.) ¶ 24; Diederich Decl. Ex. 2 (Weintraub Dep. Tr.) at 41; Diederich Decl. Ex. 3 (Sherman Dep. Tr.) at 53, 67, 109-110.

[2] All references to "Diederich Decl. Ex. ___" are to the corresponding Exhibits attached to the Declaration of Bryan R. Diederich filed herewith.

8. Major drug purchasers purchased drugs from drug manufacturers on the basis of price. Supp. Diederich Decl. Ex. 1 (Groth Dep. Tr.) at 61–62.[3]

9. Warrick was able to compete effectively in the generic marketplace for market share. *See* Diederich Decl. Ex. 1 (Weintraub Decl.) ¶¶ 17-24, 30.

C. Warrick's Generic AWPs.

10. Warrick's AWPs are set at a discount from the brand name drug. *See* Diederich Decl. Ex. 1 (Weintraub Decl.) ¶ 27.

11. When Warrick was the first to introduce a generic product, it generally set AWP at 10-20% below the equivalent brand product's AWP. Diederich Decl. Ex. 1 (Weintraub Decl.) ¶ 27; *see also* Diederich Decl. Ex. 2 (Weintraub Dep. Tr.) at 31; Diederich Decl. Ex. 3 (Sherman Dep. Tr.) at 31, 41, 56.

12. Once generic manufacturers set their AWPs, most manufacturers maintain them at constant levels. Supp. Diederich Decl. Ex. 2 (Decl. of Raymond Hartman in Opp'n to Def's Mot. for Summ. J.) ¶ 21(d).

13. Consistent with this general approach, Warrick set the AWPs for its drugs at the time of launch and, in almost all instances, left them untouched for the life of the product. Diederich Decl. Ex. 1 (Weintraub Decl.) ¶ 29.

14. Appendix A to both the Nevada and Montana complaints sets forth a list of 25 Warrick drugs for which the States seek damages, along with their AWPs reported at various points between 1997 an 2002. Of the 25 listed Warrick drugs, not a single listed drug shows a change in AWP from 1997 to 2002.

[3] All references to "Supp. Diederich Decl. Ex. ___" are to the corresponding Exhibits to the Supplemental Declaration of Bryan R. Diederich filed herewith.

D. Warrick's Marketing Practices

15. Warrick did not market the spread. Diederich Decl. Ex. 3 (Sherman Dep. Tr.) at 59-60; Diederich Decl. Ex. 2 (Weintraub Dep. Tr.) at 96-97.

16. Warrick competes based on product portfolio, production capacity, customer-service levels, and price. Diederich Decl. Ex. 1 (Weintraub Decl.) ¶ 21; *see also* Diederich Decl. Ex. 2 (Weintraub Dep. Tr.) at 41.

17. Warrick competed with other manufacturers on price by matching prices offered by competitors. Diederich Decl. Ex. 1 (Weintraub Decl.) ¶¶ 17, 24.

18. Warrick sent out price notifications listing the name of the product, its package size, its NDC, its AWP, and its "direct price," i.e., the price to the customer. Diederich Decl. Ex. 3 (Sherman Dep. Tr.) at 121. These notifications were triggered by changes in "direct prices." Diederich Decl. Ex. 2 (Weintraub Dep. Tr.) at 40.

II. THE APPLICATION OF FEDERAL UPPER LIMITS IN GENERIC DRUG REIMBURSEMENT.

19. Federal law provides that Federal Upper Limits ("FULs") are to be calculated based on the "lowest published price" for the least costly multiple-source drug in a group of equivalents. 42 C.F.R. § 447.332(b).

20. The federal regulations do not require that FULs necessarily be calculated on the basis of reported AWPs. *Id.*

21. Dennis Smith, Director of the Center for Medicaid and State Operations at CMS, testified before Congress in 2005 that "[t]o set the FUL, CMS selects lowest price (AWP, WAC or Direct Price) and multiplies it by 150% as required in regulations to arrive at the FUL." *See* Diederich Decl. Ex. 4.

22. Montana regulations require it to reimburse drugs at the lowest of "estimated acquisition cost," "maximum allowable cost" or provider's "usual and customary charge." Mont. Admin R. 37.86.1105(1).

23. Rather than calculating its own "maximum allowable cost," Montana applies the federal FULs on the list provided by CMS. Diederich Decl. Ex. 5 (Peterson Dep. Tr.) at 100–01.

24. Nevada reimburses Medicaid drugs at the lower of a State MAC, AWP less a fixed percentage, the direct price paid by the provider or the FUL. *See* Diederich Decl. Ex. 6 (Nevada Pharmacy Manual) ¶ at 51; Diederich Decl. Ex. 7 (Lawrence Dep. Tr.) 166–68; 230–31.

25. At various times, the Health Care Financing Administration ("HCFA") has instituted FULs covering reimbursement of the Subject Warrick Drugs:

a. On October 1, 1994 HCFA established an FUL effective January 1, 1995 for Perphenazine 2 mg tablets in 100 count packages (Warrick NDC 59930-1600-01[4]. *See* Diederich Decl. Ex. 8 (State Medicaid Manual, HCFA Pub. 45-6, Addendum A. Transmittal No. 26, [1994-2 Transfer Binder] Medicare & Medicaid Guide (CCH)) ¶ 42,770.

b. On October 1, 1994 HCFA established an FUL effective January 1, 1995 for Perphenazine 4 mg tablets in 100 count packages (Warrick NDC 59930-1603-01). *See id.*

c. On October 1, 1994 HCFA established an FUL effective January 1, 1995 for Perphenazine 8mg tablets in 100 count packages (Warrick NDC 59930-1610-01). *See id.*

d. On October 1, 1994 HCFA established an FUL effective January 1, 1995 for Perphenazine 16 mg tablets in 100 count packages (Warrick NDC 59930-1610-01). *See id.*

e. On October 1, 1994 HCFA established an FUL effective January 1, 1995 for Theophylline 100 mg tablets in 100 count packages (Warrick NDC 59930-1650-01). *See id.*

[4] For each FUL, the corresponding NDC follows in parentheses.

f. On October 1, 1994 HCFA established an FUL effective January 1, 1995 for Theophylline 200 mg tablets in 100 count packages (Warrick NDC 59930-1660-01). *See id.*

g. On June 1, 1996 HCFA established an FUL effective August 1, 1996 for Grisefulvin, Ultramicrocrystaline, 125 mcg tablets in 100 count packages (Warrick NDC 59930-1620-01). *See* Diederich Decl. Ex. 9 (State Medicaid Manual, HCFA Pub. 45-6, Addendum A. Transmittal No. 30, [1996-2 Transfer Binder] Medicare & Medicaid Guide (CCH)) ¶ 44,448.

h. On June 1, 1996 HCFA established an FUL effective August 1, 1996 for Griseofulvin, Ultramicrocrystaline, 250 mcg tablets in 100 count packages (Warrick NDC 59930-1621-01). *See id.*

i. On June 1, 1996 HCFA established an FUL effective August 1, 1996 for Grisefulvin, Ultramicrocrystaline, 330 mcg tablets in 100 count packages (Warrick NDC 59930-1624-01). *See id.*

j. On July 1, 1997 HCFA established an FUL effective October 1, 1997 for Albuterol Sulfate .83 mg/ml solution in 3x inhalation packages (Warrick NDC 59930-1500-06, 59930-1500-08). *See* Diederich Decl. Ex. 10 (State Medicaid Manual, HCFA Pub. 45-6, Transmittal No. 34, 1997 Medicare & Medicaid Guide (CCH)) ¶ 45,600.

k. On July 1, 1997 HCFA established an FUL effective October 1, 1997 for Albuterol Sulfate 90 mcg inhaler refills (Warrick NDC 59930-1560-02). *See id.*

l. On July 1, 1998 HCFA established an FUL effective September 1, 1998 for Theophylline 450 mg tablets in 100 count packages (Warrick NDC 59930-1670-01). *See* Diederich Decl. Ex. 11 (State Medicaid Manual, HCFA Pub. 45-6, Transmittal No. 35, [1998] Medicare & Medicaid Guide (CCH)) ¶ 150,050.

m. On April 1, 2000 HCFA established an FUL effective June 1, 2000 for Albuterol Sulfate 5mg/ml solution in 20 ml packages (Warrick NDC 59930-1515-04). *See* Diederich Decl. Ex. 12 (State Medicaid Manual, Part 6, HCFA Pub. 45-6 Transmittal No. 36, [2000] Medicare & Medicaid Guide (CCH)) ¶ 151,036.

n. On April 1, 2000 HCFA established an FUL effective June 1, 2000 for Clotrimazole 1% cream in 30 gram tubes (Warrick NDC 59930-1570-02). *See id.*

III. REIMBURSEMENT OF GENERIC DRUGS UNDER THE MEDICARE PROGRAM.

26. Under the Medicare Program, the maximum amount drugs are generally reimbursed at is 95% of AWP. *See* 42 C.F.R. § 405.517.

27. For multi-source drugs, AWP is defined as "the lesser of the median of the average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological." *Id.*

28. The median AWP has been used as one basis of generic drug reimbursement since at least 1992. *See* Supp. Diederich Decl. Ex. 3 (Decl. of Raymand S. Hartman in Supp. of Pl.'s Claims of Liability and Calculation of Damages) n.13.

29. The AWPs for the Warrick products identified in the States' complaints are sometimes at the low end of the range of products of comparable description. Addanki Aff. Attachment ¶ 63.

30. If a manufacturer reports an AWP below the median AWP for a group of multi-source drugs, that manufacturer's reporting of AWP can have caused no damage to a state. Supp. Diederich Decl. Ex. 4 (Hartman Dep.) 1370–87.

31. Plaintiffs have indicated that they intend to rely on data from the Defendants to determine the amounts paid by state consumers for Medicare co-payments. *See* Diederich Decl. Ex. 13 (Letter from Jeniphr Breckenridge to Christopher Dillon, June 1, 2006).

IV. SCHERING'S MARKETING PRACTICES.

32. Schering did not market the spread. Diederich Decl. Ex. 14 (Walsh Dep. Tr.) at 78-79, 105-106; Diederich Decl. Ex. 15 (Bishop Dep. Tr.) at 47-49; Diederich Decl. Ex. 16 (Edens

Dep. Tr.) at 25-26; Diederich Decl. Ex. 17 (Kamins Dep. Tr.) at 28-29, 97-101; Diederich Decl. Ex. 18 (Flynn Dep. Tr.) at 26, 64-66; Diederich Decl. Ex. 19 (Butler Dep. Tr.) at 34, 77-79.

33. Schering did not intend to market the spread by sending price notifications to customers. *See* Diederich Decl. Ex. 17 (Kamins Dep. Tr.) at 40-41.

34. Schering did not instruct customers to calculate the spread in sending out price notification lists. *See* Diederich Decl. Ex. 17 (Kamins Dep. Tr.) at 40-41; Diederich Decl. Ex. 20 (Longstreet Dep. Tr.) at 35-36.

35. Most of the drugs sold by both Warrick and Schering that are at issue in this case are physician administered drugs. *See* Addanki Aff. Attachment ¶¶ 24-25.

36. When drugs are self administered, physicians have no economic incentive based on AWP to prescribe one drug over another. *See* Addanki Aff. Attachment¶ 19.

Respectfully Submitted,

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By their attorneys,

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CERTIFICATE OF SERVICE

I, Christopher R. Dillon, hereby certify that a true copy of the foregoing document was served upon all counsel of record electronically pursuant to Fed. R. Civ. P. 5(b)(2)(D) and CMO No. 2 on this 8th day of February, 2007, by causing a copy to be sent to LexisNexis File & Serve for posting and notification to all counsel of record.

/s/ Christopher R. Dillon